

Appl. No. 10/810,799
Amendment dated: November 25, 2006
Reply to OA of: August 25, 2006

REMARKS

Applicants have amended claim 6 to more particularly define the invention taking into consideration the outstanding Official Action. The Examiner rejects claim 6 as indefinite under 35 U.S.C. 112, second paragraph and questions how the aqueous solution can have 100% ethanol. Applicants submit that one of ordinary skill in the art would appreciate that the solution would not contain 100% but less than 100% ethanol. Clearly, the specification supports an upper limit of 95% and therefore claim 6 has been correspondingly amended and it is believed that this amendment obviates the rejection. Accordingly, it is most respectfully requested that this rejection be withdrawn.

Applicants most respectfully submit that all of the claims now present in the application are in full compliance with 35 U.S.C. 112 and are clearly patentable over the references of record.

The rejection of claims 1-6 under 35 U.S.C. 102(b) as being anticipated by PL 167397 has been carefully considered but is most respectfully traversed.

Applicants wish to direct the Examiner's attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed.Cir. 1990).

Applicants acknowledge that as stated in the rejection, PL 167397 describes the preparation and purification of piribedil. However, Applicants most respectfully traverse the statement bridging pages 2 and 3 of the Official Action that the reference further teaches addition of water to the product, boiling the mixture, and crystallize it using 96%

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solution of ethyl alcohol to obtain a product having higher than 98% purity with reference to the process disclosed in the Example.

The presently claimed invention, as represented by claim 1, specifies a method for purifying piribedil comprising the steps of mixing a piribedil product having a piribedil purity of 98 wt% or lower with water. The resulting mixture is heated to boiling or to a temperature near boiling and ethanol is added to the hot mixture while maintaining a temperature of the resulting mixture at 60-100°C so that a clear liquid is obtained. The clear liquid is filtered and cooled resulting in a filtrate to form crystals to obtain a white solid having a piribedil purity higher than 98 wt%. On the contrary, as clearly exemplified in the Example on page 8 of the reference, the piribedil is dissolved in ethyl octane then activated carbon is added, boiled and filtered out. There is no suggestion of the claim limitations required by the present claim of using water and heating the resulting mixture to boiling or near boiling and adding ethanol to the hot mixture.

In the Example, the solvent is ethyl octane. This is filtered through a column filled with aluminum oxide and then the ethyl octane is evaporated under reduced pressure. The resulting product is then crystallized in a 96% solution of ethyl alcohol. Clearly, these limitations in no way anticipate the limitations of claim 1. Accordingly, it is most respectfully requested that this aspect of the rejection be withdrawn.

Moreover, the further limitations set forth in claims 2-6 are not anticipated by this reference. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 1-10 under 35 U.S.C. 103(a) as being unpatentable over PL 167397 has been carefully considered but is most respectfully traversed in view of the above comments.

Applicants wish to direct the Examiner's attention to the basic requirements of a prima facie case of obviousness as set forth in the MPEP § 2143. This section states that to establish a prima facie case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to

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modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Section 2143.03 states that all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Applicants also most respectfully direct the Examiner's attention to MPEP § 2144.08 (page 2100-114) wherein it is stated that Office personnel should consider all rebuttal argument and evidence presented by applicant and the citation of In re Soni for error in not considering evidence presented in the specification.

It is repeated in the obviousness rejection that claims 1-6 read on reference disclosed process as rejected above under 35 U.S.C. 102. For the reasons discussed above, this is not true and there is no suggestion of modifying the prior art procedure using the required step set forth in claim 1 of the present application. There is no suggestion or motivation to carry out the steps in the sequence performed in at least steps b) and c) of the presently claimed invention. In re Fritch, 23 USPQ 1780, 1784(Fed Cir. 1992) ("It is impermissible to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps.). Accordingly, it is most respectfully requested that this aspect of the rejection be withdrawn.

It is further urged in the Official Action that claims 7-9 differ by reciting specific concentration of ethanol in the process and claim 10 differs by reciting a specific purity

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of the product. It is then urged that it would have been obvious to one having ordinary skill in the art to prepare piribedil using the reference taught starting materials followed by the purification of the product. However, there is absolutely no suggestion as to how one of ordinary skill in the art would achieve these goals and much less the specific method steps as set forth in the claims of the present application. The necessary motivation to modify the process to obtain the presently claimed invention is not present in the prior art. Applicants specification may not be used as a teaching reference and clearly the conclusion of obviousness is based upon impermissible hindsight. Accordingly, it is most respectfully requested that this rejection be withdrawn.

In view of the above comments and further amendments to the claims, favorable reconsideration and allowance of all the claims now present in the application are most respectfully requested.

Respectfully submitted,

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